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EXAMINER

LUM, LEON YUN BON

| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,738

Applicant(s)

NICOLAU ET AL.

Examiner

Leon Y. Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-23,39-42 and 55-81 is/are pending in the application.
4a) Of the above claim(s) 55-81 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-5,7-23 and 39-42 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. The amendment filed 18 April 2005 is acknowledged and has been entered.

Election/Restrictions

2. Newly submitted claims 55-81 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: as indicated by Applicants (see page 9, 2nd paragraph of the Remarks), the newly submitted claims correspond to original claims 24-38 and 43-54, which were withdrawn following the election of claims 1-23 and 39-42 without traverse.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55-81 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In addition, it is noted that newly submitted claims 56-73 and 75-81 are improperly dependent on cancelled claims and that claim 56 includes an improper claim identifier.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-5, 7-23, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 1, lines 2-4, the phrase "a first layer comprising a molecule-adsorbing, substantially non-ablatable material which is capable of thermal degradation under laser ablation conditions" is vague and confusing. Since the first layer is substantially non-ablatable, it is unclear how the layer can be degraded by laser ablation. Is the first layer non-ablatable or ablatable?

6. Claim 40 is vague and confusing. Since the parent claim (claim 39) indicates that the first layer has a plurality of different localized areas with different molecule-adsorbing capacities, the areas would bind different molecules. Therefore, it is unclear how the areas in the instant claim have the same biomolecule adsorbed thereon.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 1, 3-5, 7-8, 11, 15-16, 21, and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (Langmuir, 1998) in view of Rowe et al (Analytical Chemistry, 1999).

Schwarz et al teach polymer substrates (i.e. first layer) laminated with a PE/PET protective layer (i.e. second layer comprising an ablative material), wherein UV-laser photoablation creates an opening in the protective layer to produce a desired microstructure (i.e. at least a portion of the second layer has been ablated to expose a surface of the first layer), wherein the photoablation creates wells with regions of the PE/PET protective layer remaining on the polymer substrate (i.e. profiled features form an informationally-addressable, predetermined pattern), wherein the patterned surface includes a 66 hole array, and wherein avidin (i.e. protein) is deposited in the holes (i.e. at least one biomolecule adsorbed on the surface of the first layer). See page 5529, left column; and Figure 1 and caption.

However, Schwarz et al fail to teach that the exposed surface of the first layer has a plurality of different localized areas having different molecule adsorbing capacities.

Rowe et al teach a patterned array of different capture antibodies immobilized on avidin-modified array surfaces, in order to test multiple samples for the presence of any of several analytes. See page 3846, right column, 2nd paragraph; page 3847, right column, 1st-2nd paragraphs; and Figure 1 and caption.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Schwarz et al with a patterned array of different

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capture antibodies immobilized on avidin-modified array surfaces, as taught by Rowe et al, in order to test multiple samples for the presence of any of several analytes. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including an array of different capture antibodies, as taught by Rowe et al, in the apparatus of Schwarz et al, since Schwarz et al teach avidin-modified surfaces, and the antibodies of Rowe et al are biotinylated to bind to avidin regions.

With regards to claim 7, Schwarz et al teach that the ablative conditions can alter hydrophobicity, hydrophilicity, or charge. See page 5527, left column, 2nd paragraph.

With regards to claim 8, Schwarz et al teach poly(ethylene terephthalate) sheets (i.e. polyethylenes and derivatives thereof). See page 5527, left column, 5th paragraph.

With regards to claims 15-16, Schwarz et al teach BSA (i.e. inert protein) on top of the PET/PE layer. See Figure 1(b) and caption.

With regards to claim 21, Schwarz et al teach 10 μm holes. See page 5529, left column.

11. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (Langmuir, 1998) in view of Rowe et al (Analytical Chemistry, 1999) as applied to claims 1 and 8 above, and further in view of Slovacek et al (US 5,340,715).

Schwarz et al and Rowe et al references have been disclosed above, but fail to teach that the first layer is polymethylmethacrylate.

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Slovacek et al teach a PMMA surface, in order to provide a suitable surface for binding of a reactant coating since PMMA has optical purity and enables proteins to be attached to the surface by simply bringing them in contact with the PMMA.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Schwarz et al and Rowe et al with a PMMA surface, as taught by Slovacek et al, in order to provide a suitable surface for binding of a reactant coating since PMMA has optical purity and enables proteins to be attached to the surface by simply bringing them in contact with the PMMA. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a PMMA surface, as taught by Slovacek et al, in the apparatus of Schwarz et al and Rowe et al, since Schwarz et al and Rowe et al teach a biosensor with optical detection methods (see Rowe et al, page 3848, right column, 2nd paragraph), and the PMMA surface taught by Slovacek et al is one example of a surface that provides optical purity that won't interfere with optical detection means.

12. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (Langmuir, 1998) in view of Rowe et al (Analytical Chemistry, 1999) as applied to claim 1 above, and further in view of Sheppard, Jr. et al (US 6,143,247).

Schwarz et al and Rowe et al references have been disclosed above, but fail to teach that the second layer is Au and can be deposited in a thin layer.

Sheppard, Jr. et al teach a substrate that is partially coated with a specific binding reagent and with a patterned reflective material that is derivatized with a

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blocking agent, wherein the reflective layer is gold metal and can be etched, in order to provide a pattern of reflective coatings that are used to orient, digitize and quantitate particles contained within a defined area of a platform by using optical elements to focus and track a central beam using reflections of side beams off of the reflective features to detect bound particles. See column 8, lines 4-8; column 17, lines 5-7; column 11, lines 64-66; column 16, line 66 to column 17, line 4; column 22, lines 27-32; and Figure 1C.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Schwarz et al and Rowe et al with a substrate that is partially coated with a specific binding reagent and with a patterned reflective material that is derivatized with a blocking agent, wherein the reflective layer is gold metal and can be etched, as taught by Sheppard, Jr. et al, in order to provide a pattern of reflective coatings that are used to orient, digitize and quantitate particles contained within a defined area of a platform by using optical elements to focus and track a central beam using reflections of side beams off of the reflective features to detect bound particles. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a gold metal layer, as taught by Sheppard, Jr. et al in the apparatus of Schwarz et al and Rowe et al, since Schwarz et al and Rowe et al teach a top layer that is composed of a material that can be etched and also teach optical detection methods (see Rowe et al, page 3848, right column, 2nd paragraph), and the gold metal layer of Sheppard, Jr. et al is one example of a material that can be etched and provides a technique for performing optical detection.

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13. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (Langmuir, 1998) in view of Rowe et al (Analytical Chemistry, 1999) as applied to claim 1 above, and further in view of Kris et al (US 6,238,869 B1).

Schwarz et al and Rowe et al references have been disclosed above, but fail to teach a glass substrate that supports the first and second layers and is part of an apparatus for performing an assay.

Kris et al teach a surface comprising a plurality of spatially discrete regions, wherein the surface is a flat surface made of glass, has a layer of polymer such as PEG and an overlaying structure that delineates the discrete regions, and wherein the surface is detected using a charge-coupled device, in order to provide an apparatus for concurrently performing multiple biological or chemical assays, and allows for high throughput analysis of multiple samples using repeated arrays of antibody probes. See column 1, lines 13-16 and 49-60; column 5, lines 3-8 and lines 41-46; column 4, lines 59-60; column 5, line 66 to column 6, line 8; column 34, lines 48-55; and Figures 2 and 5A-C.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Schwarz et al and Rowe et al with a surface comprising a plurality of spatially discrete regions, wherein the surface is a flat surface made of glass, has a layer of polymer such as PEG and an overlaying structure that delineates the discrete regions, and wherein the surface is detected using a charge-coupled device, as taught by Krist et al, in order to provide an apparatus for concurrently performing multiple biological or chemical assays, and allows for high

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throughput analysis of multiple samples using repeated arrays of antibody probes. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a glass surface, as taught by Kris et al, in the apparatus of Schwarz et al and Rowe et al, since Schwarz et al and Rowe et al teach polymer substrates, and the glass surface of Kris et al is capable of attaching to polymer substrates.

14. Claims 20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (Langmuir, 1998) in view of Rowe et al (Analytical Chemistry, 1999) as applied to claim 1 above, and further in view of Wilding et al (US 5,587,128).

Schwarz et al and Rowe et al references have been disclosed above, but fail to teach that the profiled feature is a micro-channel having a width in the range of less than 1 micron to 50 μm .

Wilding et al teach flow channels that have a cross-sectional dimension between 0.1 μm and 1,000 μm , and a width or depth on the order of about 2.0 to 500 μm , in order to connect two or more reaction chambers and to serve as access ports, inlet/outlet ports and/or vents, wherein the channels contain binding moieties such as labeled antibodies. See column 4, lines 24-26 and 37-42; and column 22, lines 13-18.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Schwarz et al and Rowe et al with flow channels that have a cross-sectional dimension between 0.1 μm and 1,000 μm , and a width or depth on the order of about 2.0 to 500 μm , in order to connect two or more reaction

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chambers and to serve as access ports, inlet/outlet ports and/or vents. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including flow channels, as taught by Wilding et al, in the apparatus of Schwarz et al and Rowe et al, since Schwarz et al and Rowe et al teach reactions wells, and the channels taught by Wilding et al connect reaction chambers.

Response to Arguments

7. Applicant's arguments, see Affidavit, filed 18 April 2005, with respect to the rejection of claims 1-23 and 39-42 by Ivanova et al (Langmuir, 2002) have been fully considered and are persuasive. The rejection of claims 1-23 and 39-42 by Ivanova et al (Langmuir, 2002) has been withdrawn.

15. Applicant's arguments, see pages 9-10 of the Remarks, filed 18 April 2005, with respect to claims 1, 4, and 39 have been fully considered and are persuasive. The rejections based on 35 U.S.C. 112, 2nd paragraph of claims 1, 4, and 39 have been withdrawn.

16. With regards to prior art, Applicant's arguments with respect to claims 1, 3-5, 7-23, and 39-42 have been considered but are moot in view of the new ground(s) of rejection. Although Applicants state that claims 1 and 39 have been amended to incorporate the features of claims 2 and 6 (see page 10, last paragraph of the

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Remarks), the amended claims include additional limitations not present in original claims 2 and 6 that necessitated the new grounds of rejection.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
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06/24/05